ENVIRONMENTAL DEFENSE
finding the ways that work

Comments on EPA's

"Concept Paper for the Nanoscale Materials Stewardship Program under TSCA"

and

"TSCA Inventory Status of Nanoscale Substances – General Approach"

In response to the US Environmental Protection Agency's request for comments published in the *Federal Register* on 12 July 2007 (72 FR 38083)

Docket #EPA-HQ-OPPT-2004-0122

Prepared by
Richard A. Denison, Ph.D.,
Senior Scientist

7 September 2007

1875 Connecticut Avenue, NW · Washington, DC 20009 · Tel 202 387 3500 · Fax 202 234 6049 · www.environmentaldefense.org
New York, NY · Oakland, CA · Boulder, CO · Raleigh, NC · Austin, TX Project Offices : Boston, MA · Los Angeles, CA

TABLE OF CONTENTS

The following comments on EPA's "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" and "TSCA Inventory Status of Nanoscale Substances – General Approach," are submitted in response to EPA's request for comments on these documents in the *Federal Register* on July 12, 2007. (Docket #EPA-HQ-OPPT-2004-0122)

I. Comments on EPA's "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA"

A. Relevant history

EPA held its first public meeting on engineered nanoscale materials on June 23, 2005. Shortly thereafter, EPA called upon its federal advisory committee, NPPTAC, to form a multi-sector work group to advise EPA on an overall approach to address the potential risks of such materials.[1] I represented Environmental Defense on that work group. EPA requested that we act quickly to complete our work on an extremely demanding schedule over the hot summer months. With all of us believing that EPA was eager to act on what we came up with – and sharing that strong sense of urgency – we worked hard to reach agreement on a proposal. We solicited and incorporated public comments on it, which were received in writing and at yet another public meeting (held on September 29), and finalized and delivered our proposal on time. After consideration by the full NPPTAC, the proposal was forwarded to the EPA Administrator in November, and promptly embraced by EPA.[2]

A core element of the work group's proposal was a framework for a voluntary program. The work group viewed the main purpose of such a program as quickly informing EPA and the public as to which nanoscale materials were in or soon to enter commerce and the extent of risk-relevant information that was available about them. It was a shared expectation that EPA would in turn expeditiously determine what additional information it should call for and what actions it should take to ensure protection of human health and the environment. The proposal called for volunteers to sign up during a period limited to 6-12 months,[3] and, for the "basic" program track, to submit requested available information and apply basic risk management practices within three months of sign-up.

As a member of the work group, Environmental Defense supported the proposal for a voluntary program because:

- It was one part of the overall proposed approach, which also encompassed a number of concurrent regulatory steps intended to provide a "backstop" to the voluntary program.
- It was to be limited in duration and completed expeditiously.
- We recognized that developing and finalizing regulatory vehicles – even if immediately initiated – would require considerable time, and that a voluntary program could – as an interim measure – both supplement and inform such vehicles.

Nearly two years have passed. During this time, the urgency for action has only grown: Hundreds of nanoscale material-containing consumer products have entered the market, and long lists of unmet research needs have been drawn up by EPA and other national and international bodies. Yet we still lack more than a cursory understanding of what nanoscale materials are or are soon to be in commerce, for what applications and in what quantities, and

what information is available about them. Had the NPPTAC proposal been acted upon by EPA as intended, the basic program would have been completed well before now.

B. EPA's current proposal

Instead, EPA has issued a new "concept paper" describing a framework for a voluntary program and is holding yet another public meeting. Why EPA felt the need to effectively start over by issuing a new proposed framework, and why it took so long to do so, is difficult to understand given that the framework EPA is now proposing is quite similar to that proposed by NPPTAC two years ago.

But of equal concern is the fact that EPA has jettisoned key elements of the NPPTAC proposal:

- No deadlines: EPA's proposal is for an open-ended program, with no deadlines for companies to sign up, deliver information or apply basic risk management practices. The only timelines identified in the concept paper are loose and apply only to EPA: it "may publish" an interim report after one year, "will develop" a report and evaluation after two years, and then will make a decision on whether to continue the program. Elsewhere, EPA indicates that an information collection schedule for the program "does not apply."[4] Nor has EPA indicated even an approximate time by which it intends to launch the program.

- No regulatory backstop: EPA's proposal does not include any mention of co-development of reporting rules under TSCA Sections 8(a) and 8(d), which the NPPTAC proposal called for and identified as a "near-term need" to provide a backstop to the voluntary program:[5] "EPA should proceed with developing appropriate TSCA Section 8(a) and 8(d) rules, coordinated with the NVP [nanoscale materials voluntary program] in a timely manner to create incentives for participation in the NVP, and obtain the needed information for EPA to carry out their responsibilities under TSCA."[6] Indeed, EPA indicated to NPPTAC in 2005 that it had *already* initiated development of such rules.[7] Yet, other than a perfunctory reference to its authority under TSCA to issue such rules,[8] EPA's documents provide no indication of any activity or intent to develop such rules.

Below are our comments on EPA's proposed "basic" and "in-depth" tracks for the NMSP.

1. The Basic Program Track

Given the absence of the essential features just described and the enormous delay, Environmental Defense is unable to support EPA's proposal for a voluntary "basic" program. At this point, we instead urge EPA to rapidly develop and implement mandatory reporting rules – a step it claimed to have initiated more than two years ago but for which there is no evidence of any actual progress. The need for these rules has only grown more apparent over the last two years in view of the extremely poor rate of participation in the United Kingdom's Voluntary Reporting Scheme (VRS), which was launched in September 2006. Nine months into that two-year program, a total of nine submissions have been made, only seven of which are from companies.[9] (Indeed, given the poor response, the UK government is itself anticipating the need

for "compulsory measures."[10]) Similarly, a voluntary survey recently conducted in Denmark yielded so little response and so little information that it did not warrant publishing.

This tepid response has led to urgent discussions at the OECD (which include USEPA representatives) as to how governments can make it easier for companies to participate in voluntary programs. Even during the NPPTAC discussions, it was a widely-held view and concern that incentives for companies to volunteer were likely very limited. Disturbingly, measures now being discussed at the OECD to increase participation include: providing even greater allowances for claiming information to be confidential and hence not to be disclosed, limiting the ways in which governments would use any information they receive, and allowing data to be submitted in any form and format – making it harder to compile, compare and share. In our view, the US and other OECD members are losing sight of a key original objective of such programs – to build public trust and confidence by making robust information available – an aim that would be severely compromised if these kinds of measures to boost participation are taken.

We are also increasingly concerned about the significant potential for participation in a voluntary program to be both limited and selective. The result could well be a highly skewed picture regarding the range of nanoscale materials in or soon to be in commerce. If, for example, only those companies that are more visible or more responsible choose to participate, then information received will be far from representative and could mislead more than it could assist.

As explained in more detail in the next section, mandatory reporting rules, in our view, are the only viable means to ensure a level playing field and submission of a comprehensive and representative set of information. Should EPA choose to proceed with a voluntary program, it should not supplant or delay development of such reporting rules. Moreover, the "basic" program track[11] should be conducted over a period of at most a few months: A month for companies to decide whether to sign up, and two months to gather and submit the request information, should be more than enough time, given that extensive public discussion of such a program has been underway for more than two years and the information to be reported is limited to that already "known or reasonably attainable."[12] As evidenced by the poor participation rate in the UK voluntary program, an open-ended program with no clear deadline for signing up only invites delay: Companies have every incentive to hang back and wait to see who will go first.

Some have argued that, should EPA decide to proceed with the NMSP, it should delay or defer promulgating section 8(a)/8(d) rules. We disagree; having rules underway would remove the incentive to "lie in the weeds" while other companies step forward voluntarily and by doing so come under greater public and governmental scrutiny. In addition, such rules enhance fairness by leveling the playing field between entities that volunteer and those that do not.

For these reasons, should EPA decide to proceed with the NMSP, it is not appropriate to delay initiation of section 8(a)/8(d) rules until after the voluntary initiative is undertaken. EPA should initiate their development immediately, as the process will take some time. Pursuing a voluntary program before initiating rulemaking simply increases the odds that substantial quantities of nanoscale materials – including harmful ones – will be in widespread commercial distribution before EPA (and the public) has any solid understanding of the extent of the problem.

2. The In-Depth Program Track

With respect to the proposed "in-depth" program track, here again other events have overtaken EPA to a significant degree. As EPA briefly notes in Annex D to its concept paper, the OECD has established a Working Party of Manufactured Nanomaterials (WPMN).[13] An explicit task now underway in the WPMN is to undertake in-depth hazard data development for representative nanoscale materials. EPA's paper does not describe how its proposal relates to this international effort. From our perspective – unless EPA can articulate a purpose and role for its proposed testing that is distinct from OECD's– it makes little sense for the US to pursue its own independent hazard testing program, and EPA's resources and efforts would be better spent in ensuring that the WPMN initiative is as robust and expeditiously executed as possible.

However, EPA's list of elements that could be contained in the "plans of action" it envisions as the product of the in-depth program track include a number of components beyond hazard testing:

- Monitoring or estimating exposures and releases;
- Evaluating the effectiveness of protective equipment or engineering controls;
- Developing a model worker education program; and

These elements, in our view, should be vigorously pursued and would not be duplicative of other efforts. We urge EPA to focus its stewardship program efforts on these components and to work closely with NIOSH in doing so. These efforts should be initiated immediately, as they do not depend on the outcomes of reporting or testing initiatives, whether voluntary or regulatory.

C. Mandatory reporting rules under TSCA Section 8 are urgently needed

To help meet the urgent need for information on nanoscale material hazards and exposures, we urge EPA to expeditiously act to use its mandatory information reporting authorities under the Toxic Substances Control (TSCA). Specifically, EPA should issue rules requiring that persons who manufacture[14] or process engineered nanoscale materials, or who propose to manufacture or process engineered nanoscale materials, submit the following:

> (i) specific information relating to the production and use of their engineered nanoscale materials, pursuant to section 8(a) of TSCA; and
> (ii) all existing hazard and exposure information on their engineered nanoscale materials, pursuant to section 8(d) of TSCA.

1. Why the need is urgent

As noted in the opening paragraph of the Environmental Protection Agency's Nanotechnology White Paper,[15]

> Nanotechnology has potential applications in many sectors of the American economy, including consumer products, health care, transportation, energy and agriculture. In addition, nanotechnology presents new opportunities to improve how we measure, monitor, manage, and minimize contaminants in the environment. While the U.S. Environmental Protection Agency (EPA, or "the Agency") is interested in researching

> and developing the possible benefits of nanotechnology, EPA also has the obligation and mandate to protect human health and safeguard the environment by better understanding and addressing potential risks from exposure to nanoscale materials and products containing nanoscale materials (both referred to here as "nanomaterials").

We concur with these views, and believe that there is considerable urgency in gaining a "better understanding" of the two elements that determine the risks presented by nanomaterials – i.e., the intrinsic hazards of nanomaterials on the one hand, and the extent of exposure on the other. As discussed at length in EPA's White Paper, the limited hazard information now available indicates that some nanomaterials may indeed pose risks to health and the environment. At the same time, exposure is likely already occurring in a growing number of workplaces and through manufacturing and use of a growing number of consumer products. As one measure, the White Paper notes that one 2005 survey identified "approximately 80 consumer products, and over 600 raw materials, intermediate components and industrial equipment items that are used by manufacturers."[16] Other sources indicate there may now be even more such products already in commerce. The consumer products inventory compiled by the Woodrow Wilson Center's Project on Emerging Nanotechnologies catalogs more than 500 "manufacturer-identified nanotechnology-based consumer products currently on the market."[17]

Some nanoscale material-containing products and applications now on the market, and others in the pipeline, can clearly result in human and environmental exposures to nanomaterials. For example, nanoscale material "fabric enhancers" – substances that make fabrics more water repellant, stain resistant, or wrinkle-resistance – reportedly have been incorporated into more than 100 clothing and interior-furnishing brands, as well as handbags, shoes, toys and home furnishings, and are being aggressively marketed to retailers of napkins and pillows.[18] Nanomaterials are also reported to be presently used applications ranging from ski waxes[19] to composite insulation that is applied in liquid form.[20] An even wider array of nanoscale material-containing products is identified as already being on the market in the Woodrow Wilson Center's consumer products inventory.[21]

These and other types of products may also entail significant exposures when considering the products' full lifecycles – that is, not just during its useful life, but also during manufacture (and manufacture of components) and disposal, recycling, or reclamation. Most obviously, significant occupational exposures can occur during production or processing, and may involve researchers in commercial and academic settings, including students. Exposures can also occur in less obvious ways. For instance, computer users are highly unlikely to inhale carbon nanotubes bound up in their computer screen, but exposure potential may dramatically increase if recyclers ultimately grind up those screens to get further use from the glass, e.g., as road aggregate. This example illustrates the importance of considering a product's complete lifecycle to understand exposures and address risks effectively.

At present, quantitative data on exposures to nanoscale materials are almost nonexistent. But the level of activity in nanotechnology suggests that occupational, consumer, and environmental exposures to nanoscale materials may be occurring in the U.S. As noted above, the White Paper cites "a [2005] survey by EmTech Research of companies working in the field of nanotechnology [that] has identified approximately 80 consumer products, and over 600 raw materials, intermediate components and industrial equipment items that are used by manufacturers,"[22]

though detailed results of this survey do not appear to be public. More informally, a Google search indicates that some nanoscale materials are also readily available for direct purchase, including nanotubes, buckyballs, quantum dots, and metal oxide nanoparticles. In mid-2005, the NanoBusiness Alliance (NBA) stated that 613 U.S. companies were involved with nanotechnology, while noting that "it is notoriously difficult to track commercial developments in nanotechnology, so we cannot be precisely sure" of this figure.[23] If anything, the number of such companies has grown substantially in the past several years. A 2006 report indicates that in Europe alone, 1538 organizations (not all companies) were registered in NanoForum's online database. A new compilation of U.S.-based entities (companies, universities, government laboratories, and other organizations) developed by the Woodrow Wilson Center, which it states is not comprehensive, contains more than 700 company entries.[24] These rough data illustrate both that there are many companies now or on the verge of making and using nanoscale materials, and that there is a compelling need for more definitive identification of such companies and their associated materials, products and applications.

Moreover, nanoscale material uses seem poised to increase significantly. Lux Research, a nanotechnology research and advisory firm, projected in 2004 that "Sales of products incorporating emerging nanotechnology will rise from less than 0.1% of global manufacturing output today to 15% in 2014, totaling $2.6 trillion."[25] Likewise, dramatic growth in the number of nanotechnology patents issued by the U.S. Patent Office in recent years suggests that growing numbers of nanoscale materials are heading for the market.[26] As the White Paper notes, "[a]s the use of nanomaterials in society increases, it is reasonable to assume that their presence in environmental media will increase proportionately, with consequences for human and environmental exposure."[27]

2. Why mandatory reporting rules rather than voluntary initiatives are essential

a. Additional, Comprehensive Information Would Enhance EPA's Ability to Meet TSCA's Objectives.

Section 8 gives the Administrator authority to require submission of information that he or she "may reasonably require for effective enforcement of [TSCA]."[28] TSCA's legislative history demonstrates that this language was intended to be read broadly. As stated by Senator Magnuson, the lead sponsor of the Senate bill and a member of the conference committee:

Used in this context 'effective enforcement of this act,' and elsewhere in the bill as well, should be used broadly. It is not meant to imply that such records and reports may only be required in order to effectively bring an enforcement action under section 16. Rather it should be interpreted to mean requiring records and gathering reports so that the authorities of the act may be indeed invoked, if necessary.[29]

As noted earlier, available information on nanoscale material hazards and exposure is far from comprehensive. These is little systematic information on the even the identity of various types of nanoscale materials now in commerce and in the pipeline for near-term commercialization, much less the quantities of those materials. Similar data gaps exist with regard to the physical and chemical characteristics of these materials; their hazardous properties; their applications and uses; exposures to them during manufacture, processing, use, or disposal.

This dearth of information makes it impossible both for EPA to meet its "obligation to ensure that potential risks are adequately understood to protect human health and the environment,"[30] and to achieve TSCA's express policy objective of "assur[ing] that innovation and commerce in chemicals substances and mixtures do not present an unreasonable risk of injury to health or the environment."[31]

Access to additional information on nanoscale material exposure and hazards would also enhance EPA's ability to carry out its statutory obligation to review new chemical substances, pursuant to the premanufacture review process established in TSCA section 5. At present, data gaps hinder both EPA's effectiveness in protecting health and environment, and its efficiency in reviewing premanufacture notices (PMNs) in a timely manner. Both the public and the nanotech industry would benefit by improving the informational database on which PMN reviews rest.

In addition, better information on potential hazard and exposure would facilitate EPA's use of its authorities under TSCA section 4 to require the generation of additional toxicity data, if warranted.[32] Such rules may be needed to effectuate TSCA's objective that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures."[33]

Finally, as EPA has observed, "information collection/dissemination actions [under TSCA] serve to facilitate implementation of media specific statutes, like the Clean Air Act."[34] Such benefits of TSCA section 8 rules should also be considered in this context.

b. Existing Regulations Will Not Provide Adequate Information.

There are no existing regulations that will produce anything approaching a comprehensive picture of nanoscale materials currently in commerce. In particular, the reporting thresholds and exemptions found in the TSCA Inventory Update Rule Amendments (IURA)[35] means that the Inventory will not provide the requisite information. Specifically, a manufacturer needed to have reported with regard to a substance only if it produced more than 25,000 pounds of that substance during 2005[36] – a threshold that few nanoscale material producers are likely to have met. With small volumes being produced by what appears to be a large number of manufacturers, a 25,000-pound-per-manufacturer-per-year threshold is likely to exclude the vast majority of nanoscale material producers. (Moreover, IUR reporting is now required only every five years, so the next Inventory update reports will not be due until 2011.[37])

Indeed, reflecting the views of most experts, EPA noted in its draft of the White Paper that, in general, quantity thresholds may not "fit" well with nanoscale materials:

> For intentionally produced nanomaterials, quantity thresholds might prove to be cumbersome given that their toxicity and reactivity do not seem to be directly proportional to quantity and size. It is also worthwhile to note that reporting systems dependent on a quantity threshold may not be directly applicable to intentionally produced nanomaterials because of the smaller quantities of nanomaterials that are

required to achieve the same or better functions as their identical larger-size chemical analogues.[38]

Just as smaller quantities of nanoscale materials can achieve the "same or better functions" compared to conventional analogues, many are likely to prove potent at far lower levels than their conventional counterparts. Both sets of attributes arise from the same cause: nanoscale materials' high surface-area-to-mass ratios and enhanced surface activity. Use of quantity thresholds developed for conventional materials cannot be assumed appropriate for engineered nanoscale materials.

In addition, "small" manufacturers are exempt from reporting under the IURA. This exemption applies to manufacturers that have total annual sales of less than $40 million and that manufacture is less than 100,000 pounds of a reportable substance, summed across all sites. Even if nanoscale material producers exceed the 25,000 reporting threshold, many are likely to trigger this exemption.

Furthermore, even manufacturers that are not exempt from reporting need provide only very limited information under the IURA. For substances produced in quantities under 300,000 pounds annually, only the following information must be reported:

- The number of workers reasonably likely to be exposed to the chemical substance at the site of manufacture or import;
- Physical form(s) of the chemical substance as it leaves the submitter's possession;
- The percentage of the total production volume associated with each physical form; and
- The maximum concentration of the chemical substance at the time it is reacted onsite to produce a different chemical substance or as it leaves the site where it is manufactured or imported.[39]

By contrast, the IURA requires reporting substantially more information for chemicals with annual production volumes of 300,000 lbs or more per site, i.e.:

- The type of processing or use operation;
- The NAICS [North American Industrial Classification System] codes that best describe the industrial activities associated with the processing or use operation;
- The industrial functions of the chemical substance during the processing or use operation;
- The percent production volume, number of sites, and number of workers associated with each processing or use/NAICS/industrial function combination;
- The commercial and consumer uses;
- The indication of the presence of the substance in consumer products intended for use by children;
- The percent of production volume associated with each commercial or consumer use; and
- The maximum concentration associated with each commercial or consumer use.[40]

However, there is no reason to believe that many if any nanoscale materials would meet this 300,000-per-site annual threshold.

Just as the IUR does not obviate the needs for reporting on use and exposure-related information under section 8(a), TSCA's automatic requirements for reporting of "substantial risk" information under section 8(e) do not obviate the need for submitting all available health and safety data under section 8(d). TSCA section 8(d) rules are needed with regard to nanoscale materials for two distinct types of reasons. First, section 8(e) only requires manufacturers and importers to provide EPA with information that "reasonably supports" the conclusion that their product "presents a substantial risk of injury to health or the environment." Experience under section 8(e) has shown that chemical producers have some difficulty determining when these thresholds are met.

Entirely apart from compliance issues with section 8(e), that provision clearly does not mandate disclosure of information indicating that a hazard does *not* exist or otherwise is not viewed as triggering the reporting requirement. Information on lack of hazard can be highly valuable, however, in furthering scientific understanding of how structurally related chemicals may behave – a particularly important attribute for nanoscale materials given the paucity of nanoscale material toxicity data at present.

In sum, existing requirements do not come close to providing an accurate, comprehensive description of nanoscale material uses/exposures, or on existing hazard information. As such, issuance of section 8(a) and 8(d) rules are needed to allow EPA to fulfill TSCA's objectives of protecting health and environment from unreasonable risks.

c. The Proposed Voluntary Nanoscale Materials Stewardship Program (NMSP) Will Not Provide Adequate Information.

The voluntary NMSP that EPA has proposed cannot provide an adequate substitute for mandatory reporting regulations, for several reasons. Even a highly successful voluntary program is unlikely to achieve 100% participation; indeed, the voluntary program itself will not even allow EPA (or the public) to determine the program's participation rate, as EPA does not currently know how many nanoscale materials are being produced by how many different manufacturers. If 100 manufacturers participate with regard to 150 materials, would those manufacturers constitute 5, 50, or 95% participation? Similarly, are the volumes voluntarily reported 5, 50, or 95% of total production? Moreover, under the program as proposed by EPA, volunteers would not necessarily agree to submit information on *all* of the nanoscale materials they produce. Thus, absent the requested section 8(a) regulations, EPA will have no means to know what fraction of a given volunteer's production of nanoscale materials (or their associated uses) is covered under that volunteer's program commitment.

Absent mandatory reporting that reaches entities that would decline to participate in a voluntary initiative, responses to these and other important questions will be little more than guesses. As a result, EPA and the public will have an incomplete – and likely highly skewed – picture of the field with respect to the range of current materials, applications and producers. If reporting requests are solely voluntary, then the most-problematic uses may well be least likely to participate. This in turn will hamper EPA's ability to expeditiously and effectively process pre-manufacture notifications for new nanoscale materials and to meet its other TSCA

responsibilities. Nor will the public be able to place any confidence EPA's ability to protect against unreasonable risks from nanoscale materials.

Finally, it is difficult to imagine how EPA could begin to conduct a meaningful evaluation of the NMSP, as it proposes to do, without being able to determine the rate of participation and the proportion of potentially available information it actually received. Unless mandatory section 8(a)/8(d) regulations have already taken effect, it will simply be impossible to make such an assessment.

3. Specific information that should be requested

EPA should issue rules under TSCA section 8(a) and 8(d) requiring producers and processors of engineered nanoscale materials to provide the information specified below. With respect to section 8(a), we do not believe this can or should be accomplished by adding engineered nanoscale materials to the agency's existing Preliminary Assessment Information Rule (PAIR), because of the limited scope of information to be reported and the overly broad exemptions and thresholds contained within the PAIR rule, as further discussed below.

a. Information Under Section 8(a)

Pursuant to the specific authorities in section 8(a), EPA should request that each person who manufactures[41] or processes engineered nanoscale materials, or who proposes to manufacture or process engineered nanoscale materials, provide the following information for each such nanoscale material insofar as it is known to the person making the report or insofar as it is reasonably ascertainable:[42]

(A) The nanoscale material's common or trade name, chemical identity, molecular structure.
(B) The categories or proposed categories of use of the nanoscale material.
(C) The total amount of each nanoscale material manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each category of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.
(D) A description of the byproducts resulting from the manufacturing, processing, use or disposal of each nanoscale material.
(E) All existing data concerning the environmental and health effects of each nanoscale material.
(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to each nanoscale material in their places of employment and the duration of such exposure.
(G) The manner of method of disposal of each nanoscale material.

As these information elements are expressly listed in TSCA section 8(a), there can be no question but that EPA has authority to request and obtain such information.

The rule should expressly include, but not be limited to, the informational elements required under a PAIR:[43]

- Quantity of chemical produced and/or imported
- Amount of chemical lost to the environment during production or importation
- Quantity of enclosed, controlled and open releases of the chemical
- Per release, the number of workers exposed and the number of hours exposed.

i. Publication of a "Preliminary Assessment Information Rule" for Nanoscale Materials Would Not Suffice.

A "Preliminary Assessment Information Rule" (PAIR) would not provide sufficient information. As noted in the preceding paragraph, PAIR covers only four information elements, and the PAIR form itself is only two pages long.[44] Moreover, PAIRs are subject to certain exemptions,[45] including:

> (A) Production or importation for the sole purpose of research and development (R&D).
>
> (B) Production or importation of less than 500 kilograms during the reporting period at single plant site.
>
> (C) Companies whose total annual sales from all sites owned by the domestic or foreign parent company are below $30 million for the reporting period and who produced or imported less than 45,400 kilograms of the chemical.

EPA should not pursue development of a PAIR that requires these exemptions, but rather should develop a less-constrained section 8(a) rule pursuant to its more general information reporting authorities as provided under 40 CFR 704. In addition to allowing for a more comprehensive set of information to be requested, such a rule could be developed without overly broad exemptions that would undermine its purpose in the context of engineered nanoscale materials, and hence would be preferable, for the following additional reasons:

> (A) *Ability to reach R&D materials* – Though R&D nanoscale materials are not, by definition, currently on the market, employees of firms engaging in R&D may well be exposed to nanoscale materials during the R&D process, and releases and disposal of R&D materials into the environment may occur. Collection of basic information as provided by section 8(a) is accordingly warranted.
>
> EPA's PAIR regulations provide a blanket exemption for R&D substances. We recognize that EPA's regulations governing reporting rules under TSCA Section 8(a) also provide an exemption for companies producing a material in small quantities solely for R&D purposes.[46] TSCA itself, however, does not mandate such an exemption. Rather, TSCA provides clear authority for EPA to require such companies to comply with Section 8(a) rules "to the extent the Administrator determines the … submission of reports … is necessary for the effective enforcement of this Act."[47] Hence, EPA can promulgate a Section 8(a) rule lacking an R&D exemption, along with an explanation of the legitimate need to include such activities in order to achieve, for engineered nanoscale materials, TSCA's express policy objective of "assur[ing] that innovation and commerce

in chemicals substances and mixtures do not present an unreasonable risk of injury to health or the environment."[48]

(B) *Not subject to the exemption for producers of less than 500 kg (1,100 pounds) of material* – As noted previously, such quantitative thresholds developed for conventional materials are not appropriate for nanoscale materials. While such an exemption is to be provided for in any PAIR developed under EPA regulations, it is not applicable to other Section 8(a) rules.

(C) *Ability to narrow the small businesses exemption* – While TSCA section 8(a) appears to require some exemption for small manufacturers, EPA should set an annual sales threshold substantially lower than $30 million/year and a production volume threshold well below 45,400 kilograms (approximately 100,000 pounds), for reasons discussed above. Given the makeup of the nanotechnology sector, failure to do so could well eviscerate the utility of the rule.

EPA has ample authority to alter the thresholds defining small businesses; see a detailed analysis in ***Appendix A***. Indeed, EPA has previously specified lower exemption thresholds in defining small manufacturers: Its section 8(a) rules for polybrominated biphenyls and tris provide exemptions based on much lower thresholds: a total annual sales level of less than $500,000 together with an annual production level of 10,000 pounds.[49]

b. Information Under Section 8(d)

Under TSCA Section 8(d), EPA has the authority to promulgate rules to require producers, importers and processors of substances to submit lists and/or copies of ongoing and completed unpublished health and safety studies with regard to materials they manufacturer, process, or distribute in commerce or that they propose to manufacture, process, or distribute in commerce. EPA should utilize this authority with regard to nanoscale materials. As EPA notes on its website,[50]

> The term "health and safety study" is intended to be interpreted broadly and means "any study of any effect of a chemical substance or mixture on health or the environment or on both," including but not limited to:
>
> - Epidemiological or clinical studies;
> - Studies of occupational exposure;
> - In vivo and in vitro toxicological studies; and
> - Ecotoxicological studies.

As all of these categories of information are highly relevant in evaluating the potential for risks from nanoscale materials, the section 8(d) rule should cover all of them. EPA should clarify that also included within the scope of the rule is information on consumer exposure, post-consumer exposure and environmental release, monitoring, biological or environmental fate and transport, and physical-chemical characterization.

II. Comments on EPA's "TSCA Inventory Status of Nanoscale Substances – General Approach"

A. New vs. existing inventory status

Environmental Defense strongly disagrees with EPA's proposed approach to determining the TSCA Inventory status of a nanoscale material the bulk form of which (with the same chemical structure) is already listed. EPA's proposed approach would effectively ignore the very nano-ness of such nanoscale materials. We have expounded at length elsewhere on this topic,[51] so we will only briefly amplify on our views here. EPA's proposed approach is not required by precedent, as EPA claims, and it reflects bad policy, plain and simple.

1. EPA's approach is not required by precedent

EPA effectively says it cannot consider particle size (and by implication, any other nano-specific characteristics) to distinguish among substances on the Inventory because it has not done so in the past. The first and simplest response to this argument is that EPA may well not have needed – or recognized that it needed – to make such distinctions before nanoscale materials came along and rendered such distinctions critically important. The real question is whether it can if it needs to. As we have documented extensively elsewhere, EPA has ample authority under TSCA to distinguish among chemical substances based on factors such as physical properties and production processes. Moreover, we have shown that it has actually done so where such factors are necessary to clearly and unambiguously identify and name a substance or distinguish among substances.[52]

In its paper, EPA maintains that "since EPA generally has not considered ***units of matter beyond molecules***, such as physical aggregates, to be reportable under the TSCA Inventory, EPA has not used particle size to distinguish for Inventory purposes two substances that are known to have the same molecular identity" (page 4, emphasis added). Putting aside EPA's erroneous equating of "molecular identity" with chemical structure,"[53] one of EPA's own examples cited in the paper one page earlier (page 3) shows that it can take into account more than strictly the chemical structure of a single molecule in distinguishing among substances: EPA indicates that it has identified different crystal lattice forms, each of which is comprised of the same molecule (the example cited is the molecule titanium dioxide), as having distinct molecular identities. It is very hard to understand why EPA was able and willing to make the distinction in this example between two super-molecular, aggregate (albeit regularly repeating) forms of the same molecule, yet says it cannot do so in the case of nanoscale vs. larger super-molecular aggregates.

2. EPA's approach is bad policy

EPA's approach is bad policy for the following reasons:

a. EPA's Approach Pretends That Nanoscale Materials Are Nothing New

Nanoscale materials are of commercial interest precisely because they have new and enhanced properties that differentiate them from their bulk counterparts (where such counterparts exist).

It is widely acknowledged, and there is mounting corroborating evidence, that such different properties also mean they can differ with respect to their biological activity. Policy that treats them as if they aren't different is illogical and flies in the face of common sense.

b. EPA's Approach Effectively Eliminates Any Possibility of Pre-market Review

There is widespread agreement, including from many in industry, that the potential risks of nanoscale materials should be examined upfront, rather than waiting until a problem develops.[54] While there is considerable debate over how best to accomplish this objective, it is incumbent on EPA to demonstrate how anything like that will take place under its proposed policy for nano forms of existing materials. Under TSCA, a decision that a chemical substance is "existing" rather than "new" has profound policy consequences: EPA's proposed approach would remove the *only* means by which any government review of the affected nanoscale materials can be assured prior to commencement of their manufacture. (This policy defect is even further exacerbated by the fact that EPA has not included any mention of using so-called "existing chemical SNURs" (Significant New Use Rules) as part of its approach. While we question the adequacy of using such SNURs (see below), some have argued that EPA can and should use them to provide an alternative means of achieving the goal of ensuring upfront review of nanoscale materials.)

c. EPA's Approach is Very Short-sighted

EPA justifies its approach by saying it will continue adhering to "the approach EPA has historically taken under TSCA" (page 2). This stance is short-sighted and hardly reassuring when we are dealing with only the first wave of a whole new class of materials for which particle size and other physical-chemical characteristics are paramount in identifying and addressing their potential risks. Most of today's nanoscale materials are variants on existing materials,[55] and so it is tempting to minimize the differences and try to get away with just tweaking the current system. Such an incremental approach to these new and rapidly evolving materials is bound to break down, and likely sooner rather than later.

EPA is clearly having difficulty acknowledging from a policy perspective that the "identity" and properties of even the current generation of nanoscale materials are dictated not only by chemical structure, but also by their physical attributes. Consider the more complex and dynamic elements expected to emerge in next-generation nanoscale materials, and mixed biological-chemical materials, and so forth. Now is the time for EPA to start thinking through how to identify and evaluate materials based on more than just chemical structure, regardless of whether they are variants of existing chemicals. Postponing the inevitable won't work when it comes to managing nanoscale materials and other anticipated advances in materials technologies.

B. Significant New Use Rules (SNURs)

Conspicuously absent from EPA's documents is any discussion of the option of using "existing chemical SNURs" as an alternative to designating nanoscale forms of existing chemicals to be new chemical substances under TSCA. But because EPA staff have discussed this option

frequently in the past, and others have promoted it,[56] we will summarize our serious concerns about the feasibility of this approach.[57]

1. Challenges to the use of SNURs

a. In Contrast to "New Chemical SNURs," "Existing Chemical SNURs" Have Rarely Been Used.

EPA has frequently issued SNURs in conjunction with its review of premanufacture notifications (PMNs) for new chemicals: more than 1,300 such "new chemical SNURs" had been issued as of the end of 2005.[58] In contrast, "existing chemical SNURs" are far rarer: EPA had issued only about 40 "existing chemical SNURs" as of May, 2006.[59] "New chemical SNURs" can be and usually are issued as direct final rules,[60] whereas "existing chemical SNURs" must proceed through full notice-and-comment rulemaking. Hence, both EPA's SNUR authorities and its history of issuing them argue, if anything, for – not against – the designation of nanoscale versions of existing chemicals as "new" chemicals, bolstered by issuance of "new chemical SNURs" where needed.

b. EPA Has Not Based Any Other "Existing Chemical SNURs" on Physical Properties.

Proponents of "existing chemical SNURs" argue that they could: (a) invoke physical characteristics and properties to distinguish nanoscale from bulk forms of the same chemicals; and (b) be issued for broad categories of nanoscale materials that share such physical attributes but do not share the same or similar chemical structures. None of the existing chemical SNURs ever issued by EPA, however, have incorporated either of these features, although some *new* chemical SNURs have used particle size in defining new uses.[61] As discussed earlier, EPA has invoked a lack of precedent as a rationale for not using physical properties like particle size to designate nano forms of existing substances to be new chemicals; a lack of precedent appears to apply to existing chemical SNURs – though not new chemical SNURs – as well.

c. A SNUR Cannot Be Used to Regulate Any Current Use.

All uses of nanoscale materials that exist at the time EPA develops a SNUR are off limits to a SNUR approach, as they are, by definition, not "new" uses.

d. EPA Has an Evidentiary Burden It Must Meet to Issue SNURs.

EPA needs to have or develop sufficient information to know which uses of a material are and are not "new," so that the criteria used to "trigger" applicability of the SNUR are clear to those potentially affected by it. To issue a SNUR, EPA must develop information on and consider several factors, including the projected production and processing volume of the chemical substance; the anticipated extent to which the new use changes the type or form, and increases the magnitude and duration, of exposure to humans or the environment associated with the new use; and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.[62] This evidentiary burden will be a greater challenge to meet in the relatively information-poor environment surrounding nanoscale materials, posing a classic *Catch-22*.

These and other serious challenges would need to be overcome were EPA to propose the use of "existing chemical SNURs" as a means to ensure that engineered nanoscale materials are effectively assessed prior to commercial introduction.

C. Failure of EPA to address exemptions from new chemical notification requirements

EPA's approach fails to address another widely acknowledged concern about the applicability of TSCA Section 5's provisions to nanoscale materials deemed to be new chemicals: the need to re-examine currently available exemptions from notification requirements and revise them to reflect the characteristics of nanoscale materials.[63] These exemptions include the Low Volume Exemption (LVE), the Low Release and Exposure Exemption (LOREX), and the Polymer Exemption (PE). The first two exemptions are based in whole or in part on mass measures that were developed for conventional substances. Experts are virtually unanimous in stating that the potential for nanoscale materials to have much greater activity per unit mass, due to increased surface area or other related factors, means that mass-based thresholds need to be developed with specific consideration of nanoscale materials and not simply carried over from those used for conventional substances. The polymer exemption is based on consideration of the bioavailability of conventional polymers. Yet evidence indicates polymer nanoparticles can enter and behave within biological systems in very different ways, so there is a pressing need to revisit the existing criteria that define exempt polymers and determine the extent to which they can be appropriately applied to polymeric nanoscale materials.

III. Conclusion

While a voluntary program made sense as a starting point two years ago when first proposed, we have concluded that it no longer does. Given the major delays in moving toward launch of such a program, and the various events that have occurred and the experience gained at home and abroad in the intervening two years, we urge EPA to move expeditiously to develop and implement mandatory reporting rules applicable to all companies producing, importing and handling engineered nanoscale materials. Such rules are necessary if EPA is to gain a comprehensive, accurate picture of the extent and nature of nanoscale materials in commerce and information available about them. And only such rules will yield a level playing field for companies and build a sense of confidence among the public that EPA is proceeding on the basis of sound information.

If EPA nonetheless chooses to pursue a voluntary reporting program, it should not supplant or delay development of mandatory reporting rules. Any such program should be of very limited duration, so as to quickly collect whatever information is to be provided by volunteers, and the selective and likely unrepresentative nature of such information should be recognized.

With respect to the "in-depth" program track, EPA should focus any testing-related efforts on ensuring that the OECD testing program is as robust and expeditiously executed as possible. EPA can and should, however, vigorously engage and assist companies in developing "plans of action" that implement protective risk management practices.

We also urge EPA to rethink its approach to determining the Inventory status of engineered nanoscale materials. In our view, EPA has ample authority and discretion to implement a sound, forward-looking policy, and should not squander an opportunity to do the right thing by an overly rigid reliance on a very narrow view of its own past practice. The most glaring defects of EPA's documents are their failure to acknowledge and consider the implications of EPA's proposed approach with respect to EPA's ability both to carry out its responsibility to ensure that engineered nanoscale materials do not pose undue risks to human health or the environment, and to keep up with the ever-accelerating pace of technology and new materials development.

Endnotes

[1] This group was the Interim Ad Hoc Work Group on Nanoscale Materials formed under the auspices of the National Pollution Prevention & Toxics Advisory Committee (NPPTAC).
[2] NPPTAC, "Overview Document on Nanoscale Materials," November 22, 2005, available online at www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf
[3] *Ibid*, pp. 10-11. A second sign-up period was to be provided for new companies or materials that emerged after the first period, or under other exceptional circumstances, but was to be implemented so as not to allow entities eligible from the outset to delay or defer signing up.
[4] See EPA's "Supporting Statement for an Information Collection Request (ICR)," Section 5(d), page 9. See also Section 6(a)(2), page 15, where EPA refers to a "three-year ICR period."
[5] NPPTAC Overview Document, *op. cit.*, p. 8.
[6] *Ibid*, p. 11.
[7] *Ibid*, pp. 2, 7 and 8.
[8] EPA, "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA," Annex C, pp. 16 and 18.
[9] See Department for Environment, Food & Rural Affairs, "Third quarterly update on the Voluntary Reporting Scheme for engineered nanoscale materials," July 2007, at www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-report3.pdf.
[10] *Ibid*, Conclusions section.
[11] We recognize that an in-depth program that entails new testing would obviously need a longer period, but urge that EPA also specify short deadlines to sign up for it and deadlines for data submission.
[12] "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA," p. 3.
[13] See the Organization for Economic Cooperation and Development's (OECD's) nanotechnology public website at webdomino1.oecd.org/comnet/env/wp-nano.nsf.
[14] The term "manufacture" throughout this document includes manufacturers, producers, and importers, consistent with TSCA's definition of the term "manufacturer" to include persons who import, produce, or manufacture. TSCA sec. 3(7), 15 U.S.C. 2602(7).
[15] U.S. Environmental Protection Agency, Nanotechnology White Paper, February 2007, EPA 100/B-07/001, p. 1 (hereinafter cited as White Paper), available at www.epa.gov/osa/nanotech.htm.
[16] White Paper, p. 4.
[17] Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, "A Nanotechnology Consumer Products Inventory," accessed Sep. 6, 2007, available at www.nanotechproject.org/index.php?id=44&action=intro.
[18] C. Stuart, *Retails drive demand for textiles, clothing*, SMALL TIMES Jan-Feb 2006, p. 9.
[19] C. Stuart, *Sports can make nano a player in other markets*, SMALL TIMES Jan-Feb 2006, p. 9.
[20] D. Forman, *Construction offers foundations for growth*, SMALL TIMES Jan-Feb 2006, p. 10.
[21] See endnote 17.
[22] White Paper, p. 4.
[23] Written testimony of Sean Murdock, NanoBusiness Alliance Executive Director, before the Research Subcommittee of the U.S. House Committee on Science Subcommittee on Research, June 29, 2005. p. 9. Available at www.house.gov/science/hearings/research05/june29/Murdock.pdf (last accessed Feb. 6, 2006).

[24] Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, data file for "Putting Nanotechnology on the Map," accessed Sep. 6, 2007, available at http://www.nanotechproject.org/file_download/191

[25] Lux Research. *"Revenue from nanotechnology-enabled products to equal IT and telecom by 2014, exceed biotech by 10 times"* (press release, October 25, 2004), a*vailable at* www.luxresearchinc.com/press/RELEASE_SizingReport.pdf (last visited Sep. 7, 2007).

[26] Koppikar V., S. Maebiusy & J. Ruttz. *Current Trends in Nanotech Patents: A View from Inside the Patent Office*. NANO LAW & BUS. J. 1(1): Article 4.

[27] White Paper, page 42.

[28] 15 U.S.C. sec. 2607(a)(1)(A).

[29] Statement by Senator Magnuson, excerpted from Congressional Record, September 28, 1976, and reprinted at p. 726 of "Legislative History of the Toxic Substances Control Act", Library of Congress, 1976. The full statement reads "Used in this context 'effective enforcement of this act," and elsewhere in the bill as well, should be used broadly. It is not meant to imply that such records and reports may only be required in order to effectively bring an enforcement action under section 16. Rather it should be interpreted to mean requiring records and gathering reports so that the authorities of the act may be indeed invoked, if necessary." Senator Magnuson was the original sponsor of the bill in the Senate and one of the TSCA conferees.

[30] White Paper, page 4.

[31] TSCA section 2(b)(3).

[32] TSCA section 4, 15 U.S.C. 2603.

[33] TSCA section 2(b)(1), 15 U.S.C. 2601(b)(1).

[34] See U.S. Environmental Protection Agency, *Overview: Office of Pollution Prevention and Toxics Programs*, January 2007, prepared by OPPT, p. 2, available at www.epa.gov/oppt/pubs/oppt101c2.pdf.

[35] 68 Fed. Reg. 847 (Jan. 7, 2003), amending 40 CFR Parts 9, 710 and 723, available at www.epa.gov/fedrgstr/EPA-TOX/2003/January/Day-07/t32909.htm (accessed Sep. 7, 2007).

[36] See EPA, Final Rule - TSCA Inventory Update Reporting Revisions, 70 Fed. Reg. 75059, 75060 (Dec. 19, 2005), available at http://www.epa.gov/fedrgstr/EPA-TOX/2005/December/Day-19/t24196.htm (accessed Sep. 7, 2007).

[37] See EPA, Final Rule - TSCA Inventory Update Reporting Revisions, *ibid.* ("EPA is amending [the Inventory Update Rule] to change the reporting cycle from 4 years to 5 years").

[38] U.S. Environmental Protection Agency, Nanotechnology White Paper – External Review Draft, 2005, p. 51, available at www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf (accessed Sep. 7, 2007).

[39] Bullets are verbatim from EPA, "Changes to IUR Since 2002 Reporting," available at www.epa.gov/oppt/iur/pubs/guidance/changes.htm.

[40] Bullets are verbatim from EPA, "Changes to IUR Since 2002 Reporting," available at www.epa.gov/oppt/iur/pubs/guidance/changes.htm.

[41] As noted above, the term "manufacturer" is used herein to include manufacturers, producers, and importers, consistent with TSCA section 3(7), 15 USC 2603(7).

[42] These information elements are taken verbatim from TSCA section 8(a), with minor grammatical modifications where warranted to reflect the fact that the request relates to nanomaterials.

[43] The PAIR form and its instructions are available at www.epa.gov/opptintr/chemtest/pubs/pairform.pdf.

[44] The PAIR form and its instructions are available at www.epa.gov/opptintr/chemtest/pubs/pairform.pdf.

[45] PAIRs also exempt "Production or importation of the listed chemical solely as an impurity, a non-isolated intermediate, and under certain circumstances as a by-product." This exemption is apparently irrelevant given that engineered nanomaterials are by definition intentionally produced and hence not impurities, non-isolated intermediates, or by-products.

[46] See 40 CFR 704.5(e).

[47] See TSCA Section 8(a)(1)(B)(ii). As discussed earlier, this section's reference to "…necessary for the effective enforcement of this Act" is intended to be construed broadly and cannot be read as constraining EPA's authority to develop a section 8(a) rule covering R&D activities.

[48] TSCA section 2(b)(3).

[49] See 45 Fed. Reg. 70728, 70730 (Oct. 24, 1980) (final Section 8(a) rules for polybrominated biphenyls and tris).

[50] EPA, "Unpublished Health and Safety Studies - TSCA Section 8(d)," available at www.epa.gov/opptintr/chemtest/pubs/sect8d.htm (accessed Sep. 5, 2007).

[51] See articles and letters posted at www.environmentaldefense.org/article.cfm?ContentID=5132.

[52] See letter from Environmental Defense to EPA General Counsel Ann R. Klee, May 22, 2006, pp. 3-6. available at www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf; and Environmental Defense, "A response to ABA's 'Regulating Nanomaterials Under TSCA Section 5,' " August 31, 2006, available at www.environmentaldefense.org/documents/5421_EnDefNanoBriefing.pdf.

[53] See letter from Environmental Defense to EPA General Counsel Ann R. Klee, *op. cit.*, pp. 3-6.

[54] See, for example, the Joint Statement of Principles of Environmental Defense and American Chemistry Council Nanotechnology Panel, submitted at EPA's June 23, 2005 public meeting, available at www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf.

[55] Overwhelmingly if measured by production volume, and possibly even by material count, nanoscale versions of existing chemical substances constitute the majority of nanoscale materials in commerce. This is why EPA's approach to the "new" vs. "existing" issue is of paramount importance.

[56] See, for example, "Regulation of Nanoscale Materials under the Toxic Substances Control Act," prepared by the Section of Environment, Energy and Resources, American Bar Association, dated June 2006, available at www.abanet.org/environ/nanotech/pdf/TSCA.pdf.

[57] For more detail, see Environmental Defense, "A response to ABA's 'Regulating Nanomaterials Under TSCA Section 5,'" *op. cit.*

[58] Personal communication from Anna Coutlakis, New Chemicals Program, OPPT, August 20, 2006.

[59] List provided by OPPT on August 22, 2006.

[60] In 1989, EPA issued regulations specifying an "expedited process" for issuing new chemical SNURs, whether in conjunction with a Section 5(e) consent order (CFR 721.160) or not following such an order (CFR 721.170). The expedited process provides for such SNURs to be issued as direct final rules in most cases. According to EPA, all but 17 of the new chemical SNURs it has issued used the expedited process, though not all of those were done through direct final rules.

[61] Our examination of the ***existing*** chemical SNURs issued to date found that none have used particle size or other such physical properties to define what constitutes a "significant new use." And all existing chemical SNURs issued for categories of chemicals apply only to substances with very similar chemical structures.

However, EPA has issued some ***new*** chemical SNURs that specifically include particle size as a characteristic that defines a "new" use; see, for example, 40 CFR 721.10010(a)(2)(ii), for Barium manganese oxide, which specifies as a new use any "manufacture, processing, or use of the PMN substance if the particle size is less than 10 microns."

[62] See Section 5(a)(2) of TSCA (15 U.S.C. 2604(a).

[63] This need was identified by NPPTAC in 2005; see NPPTAC Overview Document, p. 9, *op. cit.*

Appendix A: TSCA Section 8(a) – Addressing the Small Manufacturer Exemption

In considering the development of a reporting rule under Section 8(a) of the Toxic Substances Control Act (TSCA), the question arises as to whether EPA can waive or alter the specifics of the associated statutory exemption for small manufacturers provided therein. As explained in more detail below, while EPA may not have discretion to waive the small manufacturer exemption altogether, EPA can and has maintained elsewhere that it has discretion to limit the exemption, and a review of the legislative and regulatory history of pertinent TSCA provisions and implementing regulations supports this view.

The Statute

The TSCA small manufacturer exemption is set forth as parenthetical language in Sections 8(a)(1)(A) and 8(a)(1)(B). Section 8(a) itself contains nothing to suggest that EPA can waive the exemption in its entirety. Section 8(a)(3)(B), in fact, directs EPA, after consultation with the Small Business Administration (SBA), to "prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors."[1] At least some manufacturers, then, must be "small" under Section 8(a). As EPA itself observed in 1984, when it issued the general TSCA Section 8(a)(3)(B) standards now found in 40 C.F.R. Sections 704.3 and 704.5(f), "the establishment of a small manufacturer definition is not a discretionary action. Section 8(a) requires the establishment of a small business exemption . . . ."[2]

Pursuant to Section 8(a)(3)(A)(i), EPA has discretionary authority to "require a small manufacturer or processor of a chemical substance to submit to [EPA] such information . . . as [EPA] may require for publication of the first [TSCA Inventory]."[3] As EPA has long since published the first Inventory, however, it would appear it no longer has discretion under this provision. EPA would appear to have discretionary authority under Section 8(a)(3)(A)(ii) to issue a rule requiring even small manufacturers to report or keep records concerning a chemical that is subject to:

- a proposed or final rule under Section 4, Section 5(b)(4), or Section 6, or to an order in effect under Section 5(e); or
- relief granted as a result of civil action under Section 5 or Section 7.4.

Nanoscale materials – Proceeding Under PAIR

Under the model Preliminary Assessment Information Rule (PAIR), which EPA proposed in 1980 and issued in final in 1982,[5] a manufacturer that meets both of the following criteria is exempt from PAIR reporting as a small manufacturer: (i) aggregate total annual sales for all sites owned by the parent company of less than $30 million; and (ii) total plant site production for the reporting period of less than 100,000 pounds.[6] Also exempt are companies that, during the reporting period, manufactured or imported less than 1,100 pounds at a single site.[7] EPA included the small quantity exemption at the suggestion of "commenters."[8]

EPA did not explicitly claim in either the final or proposed PAIR that it has the authority to revise the small manufacturer exemption for a specific chemical, but it did state that both the sales and volume cut-offs could be adjusted in future PAIR rulemakings.[9] In theory, then, EPA could issue a PAIR for defined nanoscale materials and, as part of that rule, simultaneously amend the applicable small manufacturer exemption and eliminate the small quantity exemption. (EPA arguably would not be able to issue such a PAIR as a direct-final rule, as it has typically done, given its November 16, 1984, declaration that any amendments to the small manufacturer exemption (here, a revised exemption with lower cut-offs and elimination of the small quantity exemption) must be made through notice and comment rulemaking, as discussed below.)

Nanoscale materials – Proceeding Under 40 C.F.R. Part 704
(Non-PAIR, "Chemical-Specific" Section 8(a) Rules)

Like the model PAIR, the Comprehensive Assessment Information Rule (CAIR), which EPA proposed in 1986 and issued in final two years later,[10] included a regulatory exemption for small manufacturers.[11] The existing exemption in Section 704.5(f) covers manufacturers and importers: (i) whose total annual parent company sales are less than $40 million and annual plant site production volume is less than 100,000 pounds; or (ii) whose total annual parent company sales are less than $4 million.[12] Significantly, there is no 1,100-pound small quantity exemption in Part 704 as there is in the PAIR.

In the 1988 CAIR, EPA explained that "Part 704 provides the framework for all section 8(a) rules," and that "[t]he current general provisions [set forth in Subpart A] for all TSCA section 8(a) rules apply to all section 8(a) chemical-specific rules," which are listed in Subpart B.[13] EPA made two points clear:

- Notwithstanding the CAIR, EPA has the ability to issue a chemical-specific TSCA Section 8(a) rule; and
- EPA likewise has the ability to revise any of the reporting exemptions with respect to a particular chemical.

The *Federal Register* notices contain ample support for these statements.[14,15] The introductory language in Section 704.5 expressly states, for example, that "[t]his section is superseded by any TSCA section 8(a) rule that adds to, removes, or revises the exemptions described in this section."[16]

Again, the Section 704.5 introductory language comes from the November 16, 1984, final rule that established the general TSCA Section 8(a) small manufacturer exemption standards. In that final rule, EPA stated:

> EPA also has the authority to change the general exemption standards contained in this rule in appropriate cases when Agency access to necessary information is blocked by the exemption. The Agency therefore will be able to gain access to information on the production activities of the smallest manufacturers, if necessary for effective risk assessment.

> However, when changing the general exemption standards for a specific rule, EPA must follow full notice and comment rulemaking procedures with regard to the amended standards.[17]

Elsewhere in the preamble, EPA reiterated that it "can change the general exemption standards, by rule, if its information needs warrant such action."[18] To be consistent with TSCA Section 8(a)(3)(B), EPA presumably would have to consult with the SBA in developing amended exemption standards.[19]

Thus, as an alternative to proceeding under PAIR, EPA can issue, through notice and comment rulemaking, a Section 8(a) rule for defined nanoscale materials and, as part of the rule, simultaneously promulgate a small manufacturer exemption that is different from the exemption found in 40 C.F.R. Sections 704.3 and 704.5(f).

Appendix Endnotes

---

[1] TSCA § 8(a)(3)(B), 15 U.S.C. § 2607(a)(3)(B).
[2] 49 Fed. Reg. 45425, 45426 (Nov. 16, 1984).
[3] TSCA § 8(a)(3)(A)(i), 15 U.S.C. § 2607(a)(3)(A)(i).
[4] TSCA § 8(a)(3)(A)(ii), 15 U.S.C. § 2607(a)(3)(A)(ii).
[5] See 47 Fed. Reg. 26992 (June 22, 1982) (final); 45 Fed. Reg. 13646 (Feb. 29, 1980) (proposed).
[6] 40 C.F.R. § 712.25(c)(1)-(2).
[7] *Id.* § 712.25(b).
[8] 47 Fed. Reg. at 26993.
[9] *Id.* at 26996; 45 Fed. Reg. at 13654.
[10] See 53 Fed. Reg. 51698 (Dec. 22, 1988) (final); 51 Fed. Reg. 35762 (Oct. 7, 1986) (proposed). EPA rescinded the CAIR, formerly contained in Subparts C and D of Part 704, in 1995. 60 Fed. Reg. 31917, 31918 (June 19, 1995). Subparts A and B of Part 704 were unaffected by this rescission.
[11] See 40 C.F.R. § 704.5(f). As stated earlier, EPA actually promulgated Sections 704.3 and 704.5(f) small manufacturer exemption standards in 1984, pursuant to TSCA Section 8(a)(3)(B). *See* 49 Fed. Reg. 45425 (Nov. 16, 1984); 47 Fed. Reg. 27206 (June 23, 1982) (proposal).
[12] 40 C.F.R. § 704.3 (definition of "small manufacturer or importer").
[13] 53 Fed. Reg. at 51700.
[14] With respect to EPA's ability to issue a chemical-specific TSCA Section 8(a) rule, *see* 53 Fed. Reg. at 51711 ("If specific information is needed that is beyond the scope of CAIR, the Agency always has the option of issuing a chemical-specific rule for that substance."); *id.* ("should the need arise, EPA can develop a TSCA section 8(a) chemical-specific rule with questions tailored to the unique characteristics of the requesters"). Although not cited here, similar language also appears in the proposed rule.
[15] Regarding EPA's ability to revise any of the CAIR reporting exemptions for a particular substance, see 53 Fed. Reg. at 51698 (in adding substances to the rule, changes may be made when "absolutely necessary"); *id.* at 51702 ("unless the exemption is made inapplicable on a substance-by-substance basis"); *id.* ("Whenever EPA intends to change any or all of these exemptions for reporting on a particular substance, the Agency will use notice and comment rulemaking"). Once again, although not cited here, similar language also appears in the proposed rule.
[16] 40 C.F.R. § 704.5.
[17] 49 Fed. Reg. at 45426.
[18] *Id.* at 45429.
[19] See 45 Fed. Reg. 70728, 70730 (Oct. 24, 1980) (final Section 8(a) rules for polybrominated biphenyls and tris; in response to a comment from the Chemical Manufacturers Association that SBA consultation was required, EPA stated that the SBA had been consulted).